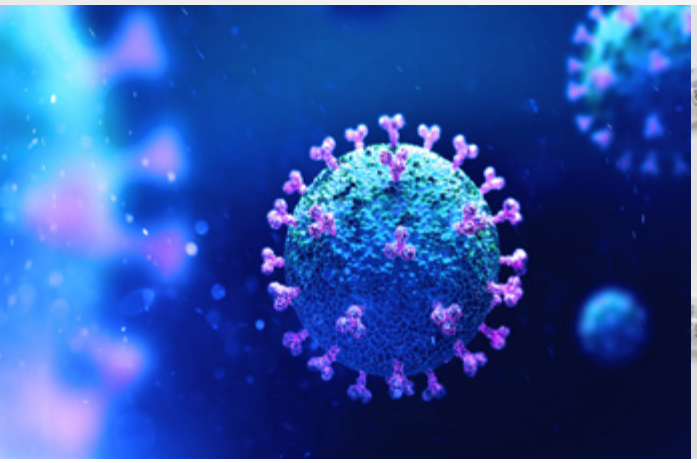
Respiratory Infections

GeneProof®

GeneProof SARS-CoV-2 Screening PCR Kit



UNIQUE SPECIFICITY AND SENSITIVITY

- Excellent QCMD panel results
- 100% diagnostic sensitivity and specificity

W.H.O. RECOMMENDED DESIGN

- Three targets (*RdRp/E/N* genes) in one reaction
- Robust and reliable screening solution for two-channel thermocyclers
- Triple protection against detection failures caused by virus mutations

MADE IN EU

- Developed and manufactured in the Czech Republic, the member of the European Union

EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents necessary
- Suitable for direct detection without NA extraction

CONTAMINATION PREVENTION

- Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating carryover contamination

ORDER INFORMATION

REF	PACKAGE
COV2S/GP/025	25 reactions
COV2S/GP/100	100 reactions

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE IVD CERTIFIED DIAGNOSTIC TEST

www.geneproof.com

ISO 13485

GUARANTEED CONTROL OVER THE COMPLETE PROCESS OF DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF ALL THE OFFERED GENEPROOF PRODUCTS

Respiratory Infections

GeneProof SARS-CoV-2 Screening PCR Kit

- GeneProof Adenovirus PCR Kit
- GeneProof Aspergillus PCR Kit
- GeneProof Bordetella pertussis/ parapertussis PCR Kit
- GeneProof Enterovirus PCR Kit
- GeneProof Chlamydia pneumoniae PCR Kit
- GeneProof Flu Multiplex PCR Kit
- GeneProof Legionella pneumophila PCR Kit
- GeneProof Mycoplasma pneumoniae PCR Kit
- GeneProof Mycobacterium tuberculosis PCR Kit

GENEPROOF COVID-19 SOLUTION

- GeneProof SARS-CoV-2 PCR Kit
- GeneProof SARS-CoV-2 Screening PCR Kit
- GeneProof SARS-CoV-2 Advanced PCR Kit

INDICATION	*in vitro* diagnostic medical device		
REGULATORY STATUS	CE IVD / EC Directive 98/79/EC		
INTENDED USER	For professional use in laboratories with trained staff		
TECHNOLOGY	Real-time PCR		
TYPE OF ANALYSIS	Qualitative		
TARGET SEQUENCE	*RdRp*, *E* and *N* genes		
ANALYTICAL SPECIFICITY	SARS-CoV-2, 100 %		
ANALYTICAL SENSITIVITY (LoD with 95% probability)	**Sample Processing**	**Sensitivity**	**Material**
	GeneProof PathogenFree RNA Isolation Kit	86.96 IU/ml	PBS
	croBEE 201A Nucleic Acid Extraction Kit	183.79 IU/ml	PBS
	Direct detection (Bi-CoV®)	417.97 IU/ml	anterior nasal swab in Bi-CoV®
	croBEE®max Nucleic Acid Extraction Kit	450.51 IU/ml	PBS
DIAGNOSTIC SPECIFICITY	100 % ($CI_{95\%}$: 95.68 % – 100 %)		
DIAGNOSTIC SENSITIVITY	100 % ($CI_{95\%}$: 91.58 % – 100 %)		
POSITIVE PREDICTIVE VALUE	100 % ($CI_{95\%}$: 91.58 % – 100 %)		
NEGATIVE PREDICTIVE VALUE	100 % ($CI_{95\%}$: 95.68 % – 100 %)		
REPORTING UNITS	IU/ml		
METROLOGICAL TRACEABILITY	1st WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146)		
EXTRACTION/INHIBITION CONTROL	PCR inhibition and RNA extraction efficiency control by Internal Control (IC)		
VALIDATED SPECIMEN	Nasopharyngeal swab (in transport media UTM (Copan), PBS or Physiological saline solution); anterior nasal swab, saliva in Bi-CoV®		
STORAGE	-20 ± 5 °C		
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree RNA Isolation Kit croBEE®max Nucleic Acid Extraction Kit		
INSTRUMENTS	croBEE Real-Time PCR System Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System CFX Connect™ / CFX96™/ Dx Real-Time PCR Detection System Mic qPCR Cycler LightCycler® 480 LineGene 9600 Plus Mic qPCR Cycler QuantStudio™ 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System		
REQUIRED DETECTION CHANNELS	FAM (RdRp/N/E), HEX/JOE/VIC (IC)		
EXTERNAL QUALITY ASSESSMENT	Regularly tested in **QCMD** and **INSTAND e.V.** External Quality Assessment Panels – results at www.geneproof.com		

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www.geneproof.com

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